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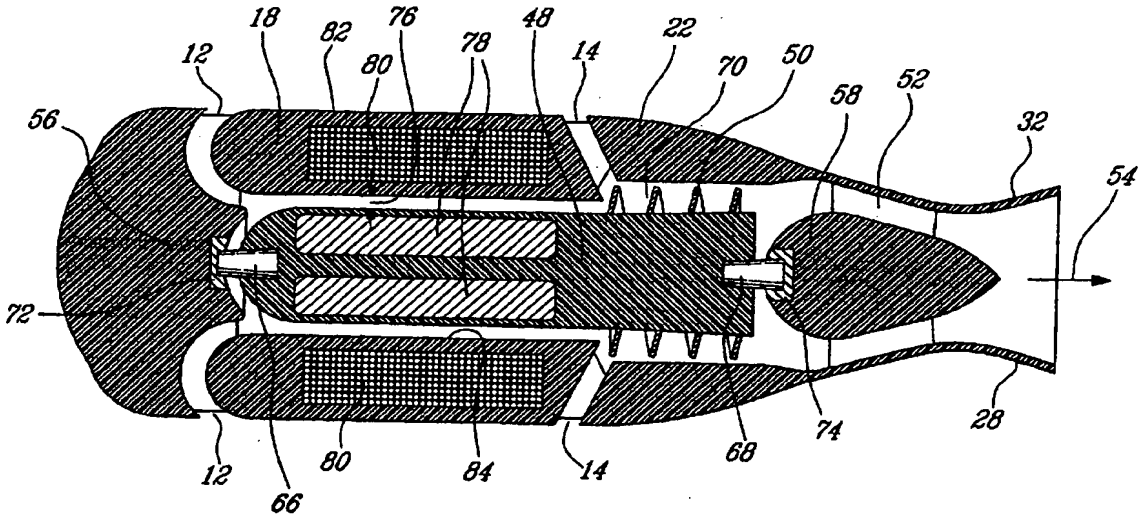


(57) Abrégé/Abstract:
A blood pump comprises a rotatable impeller shaft with an impeller blade, a cylindrical conduit, a cylindrical pump housing, a motor with a stator winding, a flow straightener, a first inlet, and a second inlet. According to a first embodiment, the rotatable impeller shaft has proximal and distal portions, the impeller blade is rigidly attached along the latter distal portion, the cylindrical conduit is adapted to contain the proximal portion of the impeller shaft, the cylindrical pump housing has proximal and distal ends and is coaxial to the conduit, the pump housing is adapted to contain the impeller blade, the cylindrical conduit extends from the proximal end of the pump housing, the motor rotates the impeller shaft, and the flow straightener is coaxial and rigidly mounted to the distal end of the pump housing. According to a second embodiment, the cylindrical conduit has proximal and distal ends, the stator winding is embedded in the conduit, the first inlet is located at the proximal end of the cylindrical conduit whereby blood flowing through this first inlet follows a first annular flow path between the conduit and the impeller shaft cooling an inside of the stator winding, the cylindrical pump housing has a proximal end, and the second inlet is located between the proximal end of the cylindrical pump housing and the distal end of the conduit whereby blood flowing through this second inlet follows a second annular flow path between the housing and the conduit cooling an outside of the stator winding.

ABSTRACT OF THE DISCLOSURE

A blood pump comprises a rotatable impeller shaft with an impeller blade, a cylindrical conduit, a cylindrical pump housing, a motor with a stator winding, a flow straightener, a first inlet, and a second inlet. According to a first embodiment, the rotatable impeller shaft has proximal and distal portions, the impeller blade is rigidly attached along the latter distal portion, the cylindrical conduit is adapted to contain the proximal portion of the impeller shaft, the cylindrical pump housing has proximal and distal ends and is coaxial to the conduit, the pump housing is adapted to contain the impeller blade, the cylindrical conduit extends from the proximal end of the pump housing, the motor rotates the impeller shaft, and the flow straightener is coaxial and rigidly mounted to the distal end of the pump housing. According to a second embodiment, the cylindrical conduit has proximal and distal ends, the stator winding is embedded in the conduit, the first inlet is located at the proximal end of the cylindrical conduit whereby blood flowing through this first inlet follows a first annular flow path between the conduit and the impeller shaft cooling an inside of the stator winding, the cylindrical pump housing has a proximal end, and the second inlet is located between the proximal end of the cylindrical pump housing and the distal end of the conduit whereby blood flowing through this second inlet follows a second annular flow path between the housing and the conduit cooling an outside of the stator winding.

TITLE OF THE INVENTION

VENTRICULAR ASSIST DEVICE COMPRISING A DUAL INLET HYBRID FLOW BLOOD PUMP.

FIELD OF THE INVENTION

The present invention relates to a cardiac assist device. More specifically, the present invention relates to a hybrid flow cardiac pump displaying characteristics of both centrifugal and axial flow pumps.

The present specification mentions a number of prior art references which are herein incorporated by reference.

BACKGROUND OF THE INVENTION

In North America, heart related diseases are still the leading causes of death. Among the causes of heart mortality are congestive heart failure, cardiomyopathy and cardiogenic shock. The incidence of congestive heart failure increases dramatically for people over 45 years of age. In addition, a large part of the population in North America is now entering this age group. Thus, the people who will need treatment for these types of diseases comprise a larger segment of the population. Many complications related to congestive heart failure, including death, could be avoided and many years added to these persons' lives if proper treatments were available.

The types of treatment available for patients of heart failure depend on the extent and severity of the illness. Many patients can be cured with rest and drug therapy but there are still severe cases that require various heart surgery, including heart transplantation. Actually, the mortality rate for patients with

cardiomyopathy who receive drug therapy is about 25 % within two years and there still is some form of these diseases that cannot be treated medically. One of the last options that remain for these patients is heart transplantation. Unfortunately, according to the procurement agency UNOS (United Network for Organ Sharing in United States), the waiting list for heart transplantation grows at a rate of more than twice the number of heart donors.

Considering these facts, it appears imperative to offer alternative treatments to heart transplantation. The treatment should not only add to a recipient's longevity but also improve his quality of life. In this context, mechanical circulatory support through Ventricular Assist Devices (VAD) is a worthwhile alternative given the large deficiency in the number of available organ donors. In the 1980's, successful experiments with mechanical hearts and VADs serving as a bridge to transplantation increased significantly. The accumulated knowledge in all aspects of patient care, device designs and related problems led to the use of VADs as permanent implants. Now, it appears appropriate to address the problem of end stage heart failure with permanent mechanical heart implants. Among the various mechanical support devices, axial flow VADs with a projected life span of five to ten years provides a very interesting approach. It is estimated that eight thousand (8,000) patients per year in Canada and seventy-six thousand patients (76,000) per year in the United States could benefit from VADs.

In 1980, the National Heart, Lung and Blood Institute (NHLBI) of the United States defined the characteristics for an implantable VAD (Altieri, F.D. and Watson, J.T., 1987, "Implantable Ventricular Assist Systems", *Artif Organs*, Vol. 11, pp. 237-246). These characteristics include medical requirements including restoration of hemodynamic function (pressure and cardiac index) avoidance of hemolysis, prevention of clot formation, infection and bleeding, and minimisation of the anti-coagulation requirement. Further technical

requirements include: small size, control mode, long life span (> 2 years), low heating, noise and vibration.

VADs can be used in several circumstances where a patient has poor hemodynamic functions (low cardiac output, low ejection fraction, low systolic pressure). Whatever the origin of the cardiac failure, the goal of the VAD is to help the heart in its pumping action. The VAD reduces the load on the heart by enhancing circulation, thus restoring the hemodynamic functions and providing improved end organ perfusion. Many devices can achieve these goals; however they are not optimal, and hemolysis and thrombus formation are still important problems requiring investigation.

In the 1970's, the first approach to the problem of mechanical support was to imitate as much as possible the heart physiology. This resulted in the development of several pulsatile devices, some of these initial designs being still in use. The first developments were pneumatically driven devices while a second generation of pumps was electrically actuated. In the 1990's, a new generation of pumps has emerged which addresses certain problems associated with previous devices (size and power consumption). These pumps are non-pulsatile devices divided into two main categories: centrifugal blood pumps; and axial flow blood pumps.

In a non-pulsatile VAD, an impeller is enclosed in a housing and continuously rotates to produce a pumping action. The faster the rotation, the higher the blood flow. These devices are called non-pulsatile or continuous because they provide for a constant blood flow. Most axial flow blood pumps operate around 10 000 RPM (Rotations Per Minute). However, in in-vivo conditions, there is a dynamic range (about 1000 RPM around the operating point) over which the output flow is pulsatile. Since the native heart is still contracting, a pressure difference between the ventricle (inlet) and the aorta (outlet) is created. This

pressure variation will produce a variation in the pump flow. The range of rotational speed (rpm) over which pulsatile flow occurs is small; at lower speed back flow is observed (in diastole) and at higher speed the load on the heart is reduced to zero. In the latter case, no pressure variation occurs resulting in non-pulsatile flow.

Many advantages are associated with the use of non-pulsatile VADs and they all have a strong impact on the physiology as well as on the clinical management. These advantages include:

Size:

Non-pulsatile VADs provide a much smaller volume than pulsatile VADs, around 25 cc for an axial blood flow pump, and 100 cc for a centrifugal pump, compared to 150 cc and more for pulsatile devices. For the sake of comparison a complete axial-flow VAD is usually smaller than the graft used for pulsatile pump. The clinical impact is the possibility to use this type of VADs in small adults as well as in children. Also, the small dimensions allow for placement of the pump in a more orthotopic position; that is, in the thorax near the heart instead of the upper abdomen. This eliminates the use of long cannula passing through the diaphragm. Furthermore, for axial flow VADs, the shape and size can be selected allowing for placement of the VAD in an intra-ventricular position.

Power:

The electrical power required to drive a non-pulsatile VAD is lower than for pulsatile VADs.

Simplicity:

Non-pulsatile VAD are mechanically simpler than pulsatile VADs;

they do not require complex structures such as valves, diaphragms, blood sacs, vents or compliance chambers. Non-pulsatile continuous VADs are made of a simple motor to which is coupled an impeller contained in an housing. One important advantage of a simple mechanical design is that it enables better durability. Durability as long as five to ten years (Nosé, Y., 1995a, "Can We Develop a Totally Implantable Rotary Blood Pump? ", *Artificial Organs*, Vol. 19, pp. 561-562; and Jarvik, R.K., 1995, "System Consideration Favoring Rotary Artificial Hearts with Blood-Immersed Bearing", *Artificial Organs*, Vol. 19, pp. 565-570) could be achieved with continuous VAD compared with two years for pulsatile VAD (Pierce, W.S., Sapirstein, J.S. and Pae, W.E., 1996, "Total Artificial Heart: From Bridge to Transplant to Permanent Use", *Ann Thorac Surg*, Vol. 61, pp. 342-346). In principle, this would allow not only to use a non-pulsatile VAD as a bridge to transplantation but also as long term mechanical support.

Hemolysis:

Hemolysis, or tearing of the red blood cells, can be estimated *in vitro* with a parameter called the Normalised Index of Hemolysis (NIH).

Infection:

Interestingly, the probability of infection is reduced with continuous VADs. This is due in large part to the transcutaneous vent of a pulsatile VADs which is an open door for opportunist infections and therefore requires daily cleaning.

Patient Issues:

Non-pulsatile VADs require less maintenance allowing the patient a greater autonomy. Also, as it is now known, most patients with a

VAD are discharged from the hospital and returned to a normal life after about a month. Presently, because of the vent in pulsatile VADs, patients cannot take a bath or swim since water could enter the motor compartment. Continuous VADs are less restrictive and allow the patient to practice more activities.

Centrifugal blood pumps were first used in cardio-pulmonary bypass for heart surgery. Based on results obtained with the Bio-Medicus pump (Medtronic Bio-Medicus Inc., Eden Prarie, MN), several groups decided to develop much smaller centrifugal pumps so that they could be totally implantable. In centrifugal blood pumps, the rotation of the impeller produces a centrifugal force that drags blood from the inlet port on top to the outlet port at the bottom side. To produce rotation of the impeller, the impeller is coupled to an electric motor. This coupling is made either (a) magnetically by means of permanent magnets located under the impeller and on the rotor of the motor or (b) mechanically by means of a shaft interposed between the impeller and the motor's rotor. Magnetically coupled devices generally show better functionality because no seal is required between the motor and the impeller shaft.

A problem related to centrifugal pumps is that although they are much smaller than pulsatile pumps, they are still too large to be totally implanted in a human thorax thus eliminating any intra-ventricular implantation.

To overcome the above-mentioned problem related to centrifugal pumps, axial flow ventricular assist blood pumps were developed. These axial flow blood pumps can decrease the hemolysis rate by decreasing the time of exposure of the blood to friction forces and by reducing the intensity of these forces. Another interesting advantage is that axial flow blood pumps are generally much smaller than centrifugal pumps.

The first commercially available axial flow blood pump was the Hemopump™ (Medtronic Inc. Minneapolis, MN) used as short term circulatory support. Based on the good results obtained with this pump, several groups have initiated the development of totally implantable axial flow VADs for long term use.

A few axial flow VADs are presently under intensive development. Examples are: the Jarvik 2000™, by the Texas Heart Institute (Houston, Texas); MicroMed DeBakey™ by MicroMed Technology (also of Houston, Texas); and HeartMate II™, by Thoratec (Pleasanton, California). All of these groups have already started in-vivo experiments on animals and humans although they still perform in-vitro trials. An overview of these pumps' operation is provided below.

Jarvik 2000™

This axial flow blood pump comprises two stators, one at the inflow and one at the outflow. These stators have two functions: they support the bearing shaft around which the impeller will rotate (middle part) and they modify the blood flow path. The inflow stator initiates the rotation of the flow so that the blade tip of the rotor does not create too much shear stress on the blood cells. The outflow stator straightens the flow so that blood from the pump enters the blood stream with a generally axial profile. Permanent magnets are enclosed in the centre of the impeller and two motor windings are located in the casing on each side of the rotor. This configuration constitutes a DC brushless motor; this is a simple and durable motor which minimises the number of mechanical parts. The power cable is connected directly to the DC brushless motor controller to change motor speed.

To implant the device, the chest is opened by means of a left thoracotomy and no cardiopulmonary bypass is used. The pump

axial outflow is anastomosed to the aorta with a Dacron™ graft. Then a ventriculotomy is made to insert the pump into the ventricle through a sewing ring attached to the apex.

Micromed DeBakey™

The Micromed DeBakey™ VAD is very similar to the Jarvik 2000™ design. Indeed, this concept of VAD is based on a DC brushless motor with blood-immersed bearings, a central impeller and two fixed side pieces. The Micromed VAD is described in U.S. patent No. 5,527,159.

Blood enters on the left side and passes through a flow straightener preventing pre-rotation thereof. Then, the blood reaches the inducer/impeller; the inducer initiates rotation of blood before this blood reaches the impeller. However, it should be noted that the impeller produces the effective pumping action. Finally, a flow diffuser converts the tangential flow into an axial flow. The inducer comprises three blades and the impeller is provided with six blades. The three blades of the inducer co-extend with three associated blades of the impeller. Each blade of the impeller contains eight cylindrical permanent magnets. Finally, a winding is placed outside the pump to complete the motor assembly, and the rotor is supported by a pair of bearings.

HeartMate II™

This pump is similar to the Micromed DeBakey™ and the Jarvik 2000™ pumps. It is placed next to the heart and is connected between the apex of the heart and the aorta. It is also a sealed-bearing type pump and, accordingly, requires a purge system. This system has a second pump which injects 15 ml/day of sterile solution

in the sealed area. A pump without purge system is now under development. Three animals have been supported for one month with the HeartMate II™ (Konishi, H., Antaki, J.F. et al., 1996b, "Long-term Animal Survival with an Implantable Axial Flow Pump as a Left Ventricular Assist Device", *Artificial Organs*, vol. 20, pp. 124-127).

Other axial flow blood pumps have been proposed. For example, U.S. patent No. 5,205,721 (Isaacson) discloses an axial flow blood pump having a hydrodynamically suspended rotor centrally positioned with respect to the stator. Hydrodynamic bearings are created by two spaces in which blood must flow to create the hydrodynamic support; this in turn produces shearing forces applied to the blood. In addition, Isaacson teaches three types of impeller blades.

In U.S. patent No. 5,211,546, Isaacson et al. teach an axial flow blood pump which is similar to that of U.S. patent No. 5,205,721. A rotor is suspended radially by hydrodynamic bearings. In certain embodiments, a radially centered thrust bearing element is provided to stabilise rotation of the suspended rotor.

US patent No. 5,290,227 (Pasque), on the other hand, proposes an axial flow blood pump having a rotor assembly described generally as a hollowed-out cylinder provided with rotor vanes which extend from the inner surface of the hollowed cylindrical rotor towards the central rotation axis of the rotor. This design generates two pumping zones inside the pump, one of these zones being an outer annulus which is expected to create substantial shearing of the blood in the outer part of the rotor.

European Patent No. EP 0 060 569 granted to Olson et al. on September 22nd, 1982 teaches a magnetically suspended and rotated impeller which comprises a bulky valve member which may be included as part of the impeller. Further,

the above patent teaches impeller blades which axially extend outside of a shroud to connect to the valve member.

In the case of pumps where the impeller blades are attached to a hollow cylindrical shaft, the shaft rotating around a fixed axle when a magnetic field is applied, the prior art reveals a secondary fluid flow path in the same direction as the primary path. A primary annular flow path is formed between the hollow shaft and the pump housing, and a secondary annular flow is formed between the hollow shaft and the supporting axle. However, these secondary annular paths have minimal flow rates and are used to insure proper lubrication of bearing faces or the clearing of regions which would otherwise collect debris.

SUMMARY OF THE INVENTION

The present invention overcomes the above and other drawbacks by providing a blood pump comprising:

a rotatable impeller shaft having proximal and distal portions, and an impeller blade rigidly attached along this distal portion;

a cylindrical conduit adapted to contain the proximal portion of the impeller shaft;

a cylindrical pump housing having proximal and distal ends, wherein the cylindrical pump housing is coaxial to the conduit and adapted to contain the impeller blade, and wherein the cylindrical conduit extends from the proximal end of the pump housing;

a motor for rotating the impeller shaft; and

a flow straightener coaxial and rigidly mounted to the distal end of the pump housing.

Also in accordance with the present invention, there is provided a blood pump comprising:

a rotatable impeller shaft having a distal portion, and an impeller blade rigidly attached along this distal portion;

a cylindrical conduit having proximal and distal ends, and being adapted to partially contain the impeller shaft therein;

a stator winding embedded in the cylindrical conduit;

a first inlet at the proximal end of the cylindrical conduit, whereby blood flowing through the first inlet follows a first annular flow path between the conduit and the impeller shaft cooling an inside of the stator winding;

a cylindrical pump housing having a proximal end, this cylindrical pump housing being coaxial to the conduit and adapted to contain the impeller blade therein; and

a second inlet between the proximal end of the cylindrical pump housing and the distal end of the conduit, whereby blood flowing through this second inlet follows a second annular flow path between the housing and the conduit cooling an outside of the stator winding.

The latter blood pump is a hybrid pump which combines the characteristics of both axial and centrifugal pumps; this hybrid pump, which is suitable for

implantation in the ventricle of a patient's heart, presents the flow characteristics of an axial pump while maintaining the throughput of a centrifugal pump.

Since the latter blood pump produces two fluid flows, one outside the stator winding and one inside these stator windings, the cooling effect exerted on the motor windings by the fluid flow is improved.

Since the blood pump has two spaced apart inlets, the possibilities of obstruction of the pump inlet is greatly reduced.

The foregoing and other objects, advantages and features of the present invention will become more apparent upon reading of the following non-restrictive description of illustrative embodiments thereof, given by way of example only with reference to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

In the appended drawings:

Figure 1 is a cross sectional view of a human heart in which an intra-ventricular hybrid flow blood pump according to an illustrative embodiment of the present invention is installed;

Figure 2 is a graph showing, for different types of pumps, curves relating the specific speed N_s with the specific diameter D_s at the point where the pump is operating at maximum hydaulic efficiency;

Figure 3 is a side elevational view of the external shape of an illustrative intra-ventricular embodiment of the hybrid flow blood pump according to the present invention;

Figure 4(a) is a side elevational and cross sectional view of an illustrative intra-ventricular embodiment of the hybrid flow blood pump according to the present invention;

Figure 4(b) is a side elevational and cross sectional view of an illustrative extra-ventricular embodiment of the hybrid flow blood pump according to the present invention;

Figure 5(a) is an enlarged, partial side cross sectional view showing the proximal mount of the drive shaft of the hybrid flow blood pump of Figure 4(a) or 4(b);

Figure 5(b) is an enlarged, partial side cross sectional view showing the distal mount of the drive shaft of the hybrid flow blood pump of Figure 4(a) or 4(b); and

Figure 6 is a schematic view of a VAD system implanted in a human being and comprising the hybrid flow blood pump of Figure 4(a).

DESCRIPTION OF THE ILLUSTRATIVE EMBODIMENT

In the following description, important aspects of the pump design are addressed. In particular, the pump design takes into consideration anatomical and physiological considerations combined with mechanical, electrical and material requirements. Then, following this discussion, global characteristics of the VAD system are presented.

It should first be noted that the hybrid flow blood pump of the present invention is not restricted to an application to an implantable VAD system. Since the hybrid flow blood pump according to the invention overcomes a number of drawbacks of the blood pumps of the prior art, those of ordinary skill in the art will understand that such a hybrid flow blood pump can be used as part of an intra-corporal system such as an intra-ventricular VAD, or an extra-ventricular VAD (for example a VAD located in the abdomen or thorax), or alternatively as a para-corporal or extra-corporal VAD (for example in a bridge to heart transplantation). It shall also be understood that the hybrid flow blood pump of the present invention can be used in temporary VADs (for example a bridge to heart transplant) or permanent VADs. A non limitative example of permanent VAD is the intra-ventricular VAD in accordance with the present invention.

In the following description, an example of permanent intra-ventricular VAD is disclosed. For certainty, it shall be understood that the concept of the hybrid flow blood pump described herein is adaptable to other types of VADs. Furthermore, it should be understood that the intra-ventricular VAD disclosed in the following description is an illustrative embodiment and hence could be modified at will within the scope of the appended claims.

ANATOMICAL PHYSIOLOGICAL AND SURGICAL CONSIDERATIONS

As previously discussed, bleeding is an important problem associated with patients who receive a VAD; in fact 30 % of patients suffer from this problem (Defraigne, J.O., Limet, R., 1996a, "Les assistances circulatoires: Partie I. Indications et description des systèmes", *Rev Med Liege*, Vol. 51, pp.295-306). The risk of infection is another quite important problem. These medical and surgical considerations are met by an illustrative embodiment of the present invention as shown in Figure 1, i.e. a completely intra-ventricular pump. This

position eliminates the need for inflow and outflow grafts and their anastomoses to thereby reduce the risk of bleeding and infection. This has also the obvious advantage of considerably reducing the implantation time. Figure 1 illustrates the proposed position of the illustrative embodiment of hybrid flow blood pump 2 in the left ventricle 4.

The hybrid flow blood pump 2 has also been designed to fit in small adults and in teens. Since the physical size and shape of the hybrid flow blood pump 2 are greatly influenced by the desired location of the pump, a good description of the ventricle anatomy is required. Feigenbaum, Harvey, "Echocardiography", 5th edition, 1994, Lea & Febiger, Philadelphia, presents several dimensions of the heart normalised by the BSA (Body Surface Area). These anatomical dimensions have been statistically determined and are known to represent 95% of the population. Taking into consideration the above-identified statistics, a ventricular dimension for humans corresponding to a BSA of 1.5 m^2 was used to design the pump.

It will be understood that the physical size and shape of the hybrid flow blood pump 2 could also be adapted to meet the anatomical dimensions of individuals falling outside this 95% of the population. Similarly, the size and shape could be adapted to specific and particular individuals and heart conditions.

For 95% of the population, the internal diameter of the left ventricle 4 ranges from 37 to 46 mm in diastole and between 22 to 31 mm in systole. This diameter is determined at the centre of the ventricular length (segment AB in Figure 1). The diameter near the apex at the first third of the ventricular length is about 1.5 cm (segment CD of Figure 1). The internal length of the ventricle from the apex to aortic valve ranges from 55 to 70 mm. Finally, the other important parameter is the surface of the aortic valve opening which ranges

from 2.5 to 4 cm^2.

From a surgical point of view, the favoured insertion procedure is to use the same approach as with valve replacement. According to this procedure, an incision is made at the root of the aorta 6 (Figure 1) and the hybrid flow blood pump 2 is inserted though the aortic valve and then into the left ventricle 4. The hybrid flow blood pump 2 is then pushed until its base reaches the myocardium at the apex 8. In order to prevent motion thereof, the hybrid flow blood pump 2 should be fixed. Also in accordance with an illustrative embodiment, an outflow cannula should pass through the aortic valves to further reduce bleeding.

One of the main roles of the hybrid flow blood pump 2 is to restore a hemodynamic function in patients with cardiac failure. Depending on the severity of the failure and the BSA, the pump 2 is susceptible to work at flow rates between 2 to 6 litres per minute (l/min) against a pressure as high as 120 mmHg and, more commonly, at a flow rate between 3 to 5 l/min against a pressure of 80 mmHg.

Another important consideration for blood pump design is the hemolysis rate. Hemolysis is the tearing of red blood cells which empties the content of the cells in the blood stream resulting in free haemoglobin; the normal level of plasma free haemoglobin is around 10 mg/dl. A blood pump with a normalised index of hemolysis (NIH) of 0.005 g/100 l and lower is considered to be almost athromatic for red blood cells. A NIH of about 0.05 g/100 l could be tolerated. A NIH situated between 0.005 g/100 l to 0.05 g/100 l is therefore envisaged for a VAD according to the present invention. A NIH as close to 0.005 g/100 l as possible is preferable. The platelets are other important blood elements; their activation by high hydromechanical forces should be avoided in order to prevent clot formation.

HYBRID FLOW BLOOD PUMP DESIGN: Mechanical aspects

This section of the disclosure is divided into parts A, B and C. Part A describes the general approach used for the selection of the pump configuration. Part B describes the external shape and size of an illustrative embodiment of the hybrid flow blood pump according to the invention, and part C describes the internal structure of this illustrative embodiment of hybrid flow blood pump.

Part A: Selection of a general pump configuration

There are three existing non-pulsating pump configurations, all turbines, and having characteristics which make them potential candidates for a cardiac blood pump: centrifugal, axial impeller and mixed. Given their relatively small diameter, cylindrical shape and high throughput, axial impeller type pumps display a number of characteristics which make them particularly well suited for implant. However, other pump configurations also exhibit characteristics, different from those of the axial impeller type pump, which would also be useful in a cardiac blood pump.

When designing turbine pumps, dimensionless characteristic values are used to compare different pump configurations. Dimensionless characteristic values provide useful indications to pump designers of expected performance regardless of the size of the pump, a comparison which would otherwise prove difficult given a virtually infinite number of operating parameters that depend on infinite variations of internal pump geometry. These dimensionless characteristic values, therefore, can be used to provide an objective starting point for the selection of a general pump configuration.

Two of these dimensionless characteristic values are the specific speed, N_s, of

the pump and the specific diameter D_s. They are defined as follows:

$$N_s = \frac{\Omega \, Q^{1/2}}{H^{3/4}} \qquad (1)$$

$$D_s = \frac{D \cdot H^{1/4}}{Q^{1/2}} \qquad (2)$$

where Ω is the rotating speed the pump in rad/s, Q is the flow rate in m^3/second, H is the head (i.e. the gain in pressure) of the pump and D the diameter of the pump, both in m. N_s remains the same regardless of the size of the pump and therefore provides an accurate measure of the performance of a given pump design. D_s relates the diameter of the rotor to a conduit having an equivalent height and throughput.

Referring to Figure 2, known are curves which relate the specific speed N_s with the specific diameter D_s at the point where the pump is operating at maximum hydraulic efficiency, hydraulic efficiency in this regard being expressed as that percentage of the power input to the pump which is translated into the energy of the movement of the fluid within the pump. Referring to Figure 2 and equation (1) above, it follows that optimally efficient pumps having a higher specific speed rotate at a higher speed and have a smaller size.

As referred to above, there are three (3) principal categories of non-pulsating pumps characterised by the direction of flow of fluid through the pump relative to the axis of rotation: axial, centrifugal and mixed.

In axial type pumps the direction of fluid flow is parallel to the axis of rotation. The pressure differential, or head, is produced by a change in amount of tangential movement. Characteristics associated with these pumps include high

throughput (Q) and small Head (H). This results in high specific speeds (N_s).

In centrifugal type pumps a large portion of the throughput, either on the outlet or the inlet, is radial, i.e. perpendicular to the axis of rotation. This change in direction causes an increase in pressure. Contrary to axial type pump, the centrifugal type pump is characterised by relatively large Head (H) and smaller throughput, resulting in low specific speeds.

Located between centrifugal type pumps and axial type pumps are mixed type pumps where the direction of flow at the output or input is composed of both radial and axial components. As would be expected, the specific speed of mixed type pumps is located between the other two.

In order to determine an optimised choice for a pump, it is necessary to evaluate the specific speed N_s in light of the characteristics in terms of head and throughput projected for the pump. As discussed above, the pump will typically be operated using a throughput of 5 l/min and a head of approximately 100 mmHg. Additionally, current motor technology provides small yet efficient motors operating at a speed of 11,000 RPM. This gives a specific speed of 1.62.

Referring again to Figure 2, an indication is given to the ranges of N_s and D_s within which a given pump configuration will provide efficient operation. The specific speed N_s of 1.62 falls within a transition region of the curve between axial flow and radial flow pumps and therefore either an axial flow, a radial flow or a mixed pump flow will prove adequate. However, a mixed (or hybrid) flow pump topology would yield a higher efficiency than purely radial or axial flow pumps such as the above discussed Jarvik 2000™ or Micromed Debakey™ pumps. Additionally, the specific diameter D_s is around 2 which, by applying equation (2) above, yields a characteristic diameter of 9.83×10^{-3} for the pump,

i.e. a very small pump.

Part B: External design requirements

The external design (shape and size) of the hybrid flow blood pump 2 (Figure 1) depends on the anatomic dimensions of the left ventricle 4. Figure 3 illustrates the external shape of the hybrid flow blood pump 2 and the critical geometric parameters thereof.

Pump Inlets

Figure 1 shows that the illustrative embodiment of the axial flow blood pump 2 rests at the bottom of the left ventricle 4, in the region of the apex 8 of the heart 30. Referring now to Figure 3, in order to prevent the inner walls of the left ventricle 4 from completely obstructing blood intake, inlets fore 12 and aft 14 are provided. Additionally, the distal end of the pump is in the shape of a hemisphere 16. The diameter of the hemisphere 16 is set to approximately 20 mm, which is smaller than the segment CD (see Figure 1) and suitable to limit the level of pressure on the walls of the left ventricle 4 near the apex 8.

The first inlet 12 is found at the proximate end of the pump 2 between the hemisphere 16 and the cylindrical conduit 18 which also provides the housing for the stator windings. A first series of narrow supports 20 spread out evenly around the axis of the pump 2 joins the hemisphere 16 to the cylindrical conduit 18.

The second inlet 14 is formed between the cylindrical conduit 18 and an impeller housing 22. A second series of narrow supports 24 spread out evenly around the axis of the pump joins the cylindrical conduit 18 to the impeller housing 22. The impeller housing 22 covers only the distal portion of the pump

2 such that the second inlet 14 is axially spaced apart from the first inlet 12. The separation of the inlets 12 and 14 reduces the effect occlusion of one of the pump inlets may have on normal operation of the pump 2.

Outflow Cannula

Referring back to Figures 1 and 3, at the distal outflow end of the hybrid flow blood pump 2, the outflow diameter 26 (see Figure 3) is reduced so as to reduce as much as possible the obstruction caused by an outflow cannula 28 to the operation of the aortic valves (not shown); since the function of the hybrid flow blood pump 2 is to assist blood circulation, blood flow contribution from the natural contraction of the heart 30 should be maintained. In an illustrative embodiment, the area of the outflow cannula 28, corresponding to diameter 26, is of 1.3 cm^2.

As can be better seen from Figure 3, a blood diffuser 32 is formed at the distal end of the cannula. The function of diffuser 32 is to reduce the shear stress on blood cells. Without diffuser 32, the velocity of blood ejected from the pump 2 is higher than the velocity of blood ejected from the heart 30. The difference in velocity between these two blood flows will result in shear stress proportional to this difference. Since the velocity is inversely proportional to the cross-sectional area, a solution for reducing the relative velocity of the blood flows from the pump 2 and from the heart 30 is (a) to increase the area of the orifice 34 of the cannula 28 to reduce the velocity of the flow of blood from the pump 2, and (b) to decrease the area occupied by the blood flow from the heart to increase the velocity of the latter blood flow. This is exactly the role of diffuser 32. Of course, parameters such as the angle of opening and the length of the diffuser 32 can be adjusted at will to fit the mechanical characteristics of the pump 2 in view of minimising the shear stress on the blood cells.

Housing

The diameter of the hybrid flow blood pump 2 is a compromise between pumping requirements and minimal interference with heart contraction. In an illustrative embodiment, the maximum allowable diameter 36 is about 22 mm which is the diameter of the left ventricle 4 in systole. This dimension is reasonable since people with heart failure generally have dilated ventricles.

The maximum length 38 of the hybrid flow pump 2, as illustrated in Figure 2, is set in regard of the average distance between the apex 8 and the aortic valve 40 of the heart 30. In an illustrative embodiment, the length 38 of the axial flow blood pump 2 is about 55 mm. As shown in Figure 1, a reduction of the pump diameter (see 40) toward the outflow increases the aortic valve clearance in order to minimise interference with the aortic valve function.

Since in this illustrative embodiment the hybrid flow blood pump 2 will be completely located inside the left ventricle 4, blood will circulate around the pump 2. As a consequence, all external surfaces of the pump 2 should be as smooth as possible and avoid as much as possible abrupt deviations to thereby minimise vortices, turbulence and recirculation zones which may be at the origin of clot formation. To overcome this problem, the pump 2 and other components may be machined from surgical quality titanium.

Fixation Mechanism

At the pump inflow, a fixation mechanism 42 is provided. As an example, fixation mechanism 42 comprises:

- an elongated needle member 44 which is driven from the inside of the left ventricle 4 through the myocardium and the epicardium at the apex 8 of the

heart 30; and

- a fixation disk 46 fastened to the free end of the needle member 44 on the outside of the heart 30 to firmly fix the hybrid flow blood pump 2 in place.

Of course, it is within the scope of the present invention to employ any other type of fixation mechanism.

Electrical Supply

The required electrical supply for the operation of the motor (to be described herein below) is made through a wire that could, for example, extend from the pump 2 along the needle member 44 to reach the controller and the energy source.

Part C: Internal design characteristics

In the design of the internal components, some of the characteristics of axial flow blood pumps have been retained and combined with some of the characteristics of centrifugal pumps to form the hybrid pump.

Referring to Figure 4(a), it should be first mentioned that the hybrid flow blood pump 2 comprises a stationary housing structure comprising the impeller housing 22, the cylindrical conduit 18, an impeller shaft 48, an impeller 50 and a stationary outflow stator 52.

At the outflow, the stationary outflow stator 52 is used to transform the rotational motion of the flow about the longitudinal axis 54 into a translational motion; in other words, the outflow stator acts as a flow straightener.

Current wet motor axial flow blood pumps use permanent magnets inserted either in the central hub or in the impeller blades. Both methods require important compromises. Insertion of the permanent magnets in the central hub requires a large hub to locate the permanent magnets close to the motor windings for obvious electromagnetic coupling reasons; in contrast, a small hub has the advantage of increasing the pumped blood volume. Insertion of the permanent magnets in the impeller blades yields a compromise since the geometry of the blades must be curved for pumping efficiency. As a consequence, some of the embedded magnets move away from the windings as the blade curves.

In the approach proposed in the present specification, the hybrid flow blood pump 2 presents an enclosed-impeller hybrid flow configuration. In the illustrative intra-ventricular embodiment of this configuration as illustrated in Figure 4(a), the impeller 50 comprises a spiralling auger type impeller blade 70 (characteristic of an axial pump) rigidly attached to the impeller drive shaft 48 and enclosed in the impeller housing 22. The impeller blade 70 fits snugly into the confines of the impeller housing 22.

Still referring to Figure 4(a), at both ends of the impeller drive shaft 48 end pivots 66 and 68 protrude. The function of the end pivots 66 and 68 is to support the impeller drive shaft 48 at each end. The end pivots 66 and 68 are respectively inserted into respective bushing mounts 56 and 58. Bushing 72 is mounted on the inflow bushing mount 56. In the same manner, bushing 74 is mounted on the outflow bushing mount 58 which is held rigid by the outflow stator 52. The bearings formed by the bushing and pivot assemblies 66, 72 and 68, 74 are the only mechanical parts subject to wear. Therefore, these parts are expected to be mostly responsible for the life span of the hybrid flow blood pump 2.

Of course, the shape (curvature and angulation) of the impeller blade 70 should be optimally determined in relation to pumping performance and other hydrodynamic considerations. In particular, the influence of the blade angulation on the level of shearing stresses, turbulence and cavitation responsible for red blood cell damage and increase of hemolysis rate must be carefully taken into consideration.

Still referring to Figure 4(a), the gap 76 separating the impeller drive shaft 48 and the inner surface of the cylindrical conduit 18 should be sufficiently large to produce sufficient blood flow in order to increase washout and prevent clot formation. On the other hand, too large a gap 76 may either reduce the pump efficiency or result in higher hemolysis.

Referring back to Figure 1 in addition to Figure 4(a), in the illustrative embodiment the volume of blood entering the second generally radial inlet 14 (characteristic of a centrifugal pump), typically four (4) l/min, is higher than the volume of blood entering the first generally axial inlet 12 (characteristic of an axial pump), typically one (1) l/min. A number of benefits can be associated with the increased throughput of blood at the second inlet 14. For example, installation of a pump 2 in the left ventricle 4 of a patient with the diffuser 32 inserted in the aortic valve generally interferes with the proper operation of the valve. Optimally, it would be preferred if the aortic valve would continue to function normally, however in some cases the aortic valve ceases to function further, and instead remains closed around the cannula 28. Typically, blood would have the tendency to collect in the region close to the aortic valve and the cannula 28 which might lead to thrombus formation and other adverse effects. The increased volume of blood entering the second inlet 14 has the effect of creating turbulence in the region within the ventricle 4 bordered by the aortic valve and the cannula 28, thus providing improved washout of this region and thereby reducing the effects of the malfunctioning aortic valve

As previously mentioned, the pump design should minimise shearing stress in order to minimise hemolysis. In that context, reduction of the rotational speed would obviously contribute to reduce hemolysis. However, reduction of the rotational speed while pumping the same volume of blood requires an increase of the volume of blood contained in the rotor zone of the pump 2. The volume of blood contained in the rotor zone can be increased by either increasing the diameter of the rotor zone, or alternatively minimising the volume of the central hub of the pump rotor.

Design of the internal surfaces of the pump is also important for minimising shearing stress in order to minimise hemolysis. Figure 5(a) shows the configuration of the region between the proximal bushing mount 56 and the impeller drive shaft 48. Figure 5(b) shows the configuration of the region between the impeller drive shaft 48 and the outflow bushing mount 58.

Referring to Figure 5(a), the proximal surface 60 of the impeller drive shaft 48 is curved as is the inside distal facing surface 62 of the proximal bushing mount 56. Forming the surfaces in this manner reduces the shearing stress placed on the blood thus minimising hemolysis (see flow 61). A similar curve 64 is placed on the outflow bushing mount 58 to reduce shearing stress at the outlet (see Figure 5(b), in particular flow 65).

Additionally, referring to both Figures 5(a) and 5(b), end pivots 66 and 68 by which the proximal and distal ends of the impeller shaft 48 are mounted to their respective bushing mounts 56, 58 are slightly tapered towards the proximal end of the pump 2. This helps prevent the creation of eddies and the collection of debris in proximity to the end pivots. Normally, a taper of the order of five degrees (5°) is adequate.

Referring now to Figure 4(b), an alternative, illustrative extra-ventricular embodiment of hybrid flow blood pump 100 adapted for use externally of the heart as a ventricle bypass/assist will now be described. In this embodiment the pump 100 would typically be implanted above the diaphragm in the thorax and would be connected to the circulation system using standard vascular grafts, a first graft 102 being attached to the inlet or proximal end of the pump and a second graft 104 being attached to the outlet or distal end of the pump 100.

Similar to the illustrative embodiment of the hybrid flow blood pump 2, the alternative illustrative embodiment 100 of hybrid flow blood pump as illustrated in Figure 4(b), comprises a stationary housing structure including an impeller housing 106, a cylindrical conduit 108, an impeller shaft 110, an impeller 112 and a stationary outflow stator 114.

The impeller 112 comprises a spiralling auger type impeller blade 116 rigidly attached to the impeller drive shaft 110 and enclosed in the impeller housing 106. The impeller blade 116 fits snugly into the confines of the impeller housing 106.

A series of longitudinal ridges 118, typically five (5) evenly spaced around the pump axis 119, support the cylindrical conduit 108 within the impeller housing 106 thereby forming a series of longitudinal flow passages as in 120 between the cylindrical conduit 108 within the impeller housing 106.

The longitudinal ridges 118 extend to meet and hold rigid the inflow bushing mount 122 with respect to the impeller housing 106 and the circular conduit 108. Similarly, the outflow bushing mount 124 is supported by the distal portion of the impeller housing 106 through the stationary outflow stator 114.

At both ends of the impeller drive shaft 110 end pivots 126 and 128 protrude.

The end pivots 126 and 128 are respectively inserted into respective bushings 130 and 132 to support the impeller drive shaft 110 within the cylindrical conduit 108 while at the same time allowing the impeller drive shaft to rotate freely. Bushing 130 is mounted on the inflow bushing mount 122. In the same manner, bushing 132 is mounted on the outflow bushing mount 124.

In addition to the series of longitudinal flow passages 120, an annular flow passage 134 is formed between the inner surface 136 of the cylindrical conduit 108 and the outer surface 138 of the impeller drive shaft 110.

Electrical Aspects

Referring to Figure 4(a), the hybrid flow blood pump 2 will be actuated in an illustrative embodiment by means of a brushless DC (direct current) motor. This brushless configuration presents the advantage of minimal wear. Two other interesting characteristics of brushless DC motors are high rotational speed and high torque.

In the hybrid flow blood pump 2, the brushless DC motor is composed of elongated axial permanent magnets 78 inserted in the impeller shaft 48 and stator windings 80 embedded in the cylindrical conduit 18.

As discussed previously, the gap 76 between the impeller shaft 48 and the cylindrical conduit 18 must be sufficiently large to produce sufficient blood flow in order to increase washout and prevent clot formation. However, increasing the gap 76 decreases the efficiency of the coupling between the permanent magnets 78 and the stator windings 80. This requires an increase in current through the stator windings 80 to compensate for the decreased efficiency and to maintain the same characteristics in terms of impeller blade speed and blood volume throughput. Increase in current leads to an increase in thermal loss on

the surface of the stator windings 80, this thermal loss increases as the square of the current through the stator windings 80. As the temperature of the surface of the stator windings must remain at or below 40°C, the gap 76 must be sufficiently small to provide efficient coupling between the permanent magnets 78 and the stator windings 80.

Thermal performance is also improved given the proximate nature of the stator windings 80 to the external surface 82 of the conduit 18. Blood flow over the external surface 82 provides cooling effect for the stator windings 80 in addition to that provided by the blood flow within the gap 76 between the impeller shaft 48 and the inner surface 84 of the conduit 18.

The alternative embodiment of the hybrid flow blood as illustrated in Figure 4(b) maintains the essential electrical characteristics of the illustrative embodiment of Figure 4(a) with the exception that, referring to Figure 4(b), the design of the pump 100 overcomes the thermal limitations by allowing for a second blood flow passage along the series of longitudinal flow passages 120 between the impeller housing 106 and the cylindrical conduit 108.

Axial spacing between the impeller and the permanent magnets along the drive shaft enables separate design of the DC motor and the impeller to obtain simultaneously both efficient coupling between the permanent magnets and the stator windings and sufficient pumping volume.

Selection of the Materials

The choice of materials for an implantable device is crucial and several properties of the available materials should be considered: strength, durability, hardness, elasticity, wear resistance, surface finish and biocompatibility. Biocompatibility is very important to minimise irritation, rejection and

thrombogenesis. The interaction between the surface of the material and the biological tissues is very complex. In several cases, treatments of the surface with human proteins, certain drugs like heparin or other biocompatible material may considerably increase the biocompatibility and minimise thrombus formation.

VAD SYSTEM

Figure 6 schematically illustrates an embodiment of implantable VAD system including an axial flow blood pump 2. The VAD system is composed of four main parts:

- the axial flow blood pump 2 implanted in the left ventricle 4 of the patient 86;
- an internal controller 88;
- two energy sources, namely an internal rechargeable battery 90 and an external rechargeable battery 92; and
- a Transcutaneous Energy and Information Transmission (TEIT) system 94.

VAD and TEIT Systems are well known in the art and will not be further discussed in the present specification.

To conclude, ventricular assist devices (VADs) are now being used world-wide and their utilisation is becoming more and more accepted as a solution to treat end stage heart failure. It is generally accepted that VADs extend life of patients while improving quality of life of these patients. A poll, made with patients who received VADs, concerning their quality of life revealed that these patients would have preferred a heart transplant but prefer their situation than

having to be on dialyses.

It is also now being accepted that VAD is becoming a cost effective solution considering the fact that patients are discharged from the hospitals more rapidly and may return to normal life occupations. In the United States, several insurance companies are now reimbursing the implantation of VADs.

Finally, the axial flow blood pump 2 according to the invention provides an excellent bridge to heart transplant and aims at long term implant. The new proposed axial flow blood pump 2 should answer most of the remaining problems and limitations of the prior art axial flow blood pumps, especially those related to hemolysis and bleeding.

Although the present invention has been described hereinabove by way of illustrative embodiments thereof, these embodiments can be modified at will, within the scope of the appended claims, without departing from the spirit and nature of the present invention.

WHAT IS CLAIMED IS:

1. A blood pump comprising:

a rotatable impeller shaft having proximal and distal portions, and an impeller blade rigidly attached along said distal portion;

a cylindrical conduit adapted to contain the proximal portion of said impeller shaft;

a cylindrical pump housing having proximal and distal ends, wherein said cylindrical pump housing is coaxial to said conduit and adapted to contain said impeller blade, and wherein the cylindrical conduit extends from the proximal end of the pump housing;

a motor for rotating said impeller shaft; and

a flow straightener coaxial and rigidly mounted to the distal end of said pump housing.

2. A blood pump comprising:

a rotatable impeller shaft having a distal portion, and an impeller blade rigidly attached along said distal portion;

a cylindrical conduit having proximal and distal ends, and being adapted to partially contain said impeller shaft therein;

a stator winding embedded in said conduit;

a first inlet at the proximal end of said cylindrical conduit, whereby blood flowing through said first inlet follows a first annular flow path between said conduit and said impeller shaft cooling an inside of said stator winding;

a cylindrical pump housing having a proximal end, said cylindrical

pump housing being coaxial to said conduit and adapted to contain the impeller blade therein; and

a second inlet between the proximal end of the cylindrical pump housing and the distal end of said conduit, whereby blood flowing through said second inlet follows a second annular flow path between said housing and said conduit cooling an outside of said stator winding.

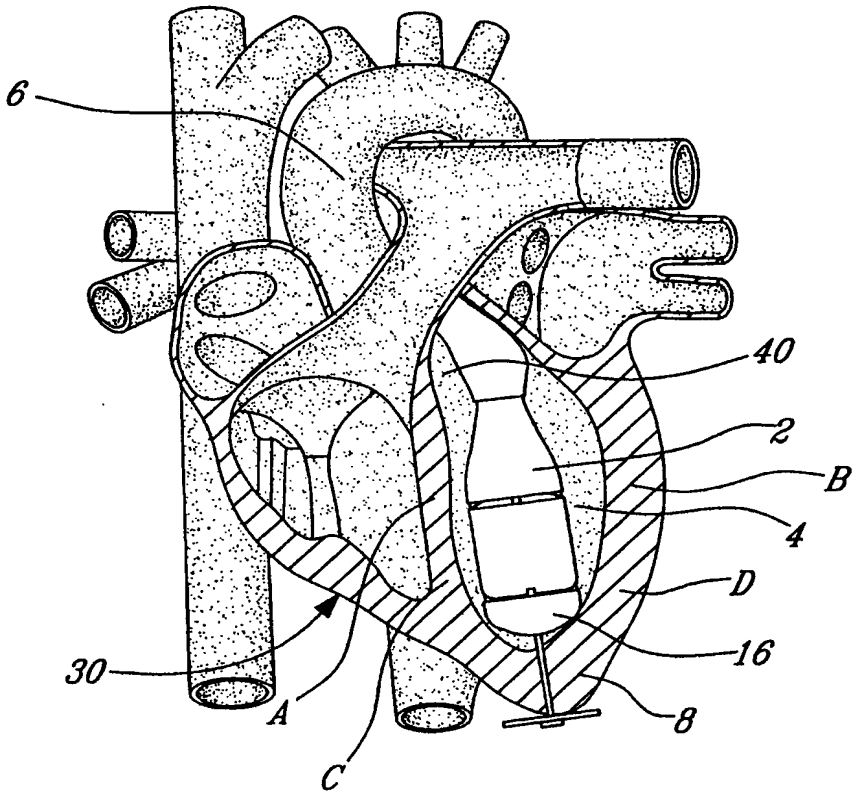


Fig. 1

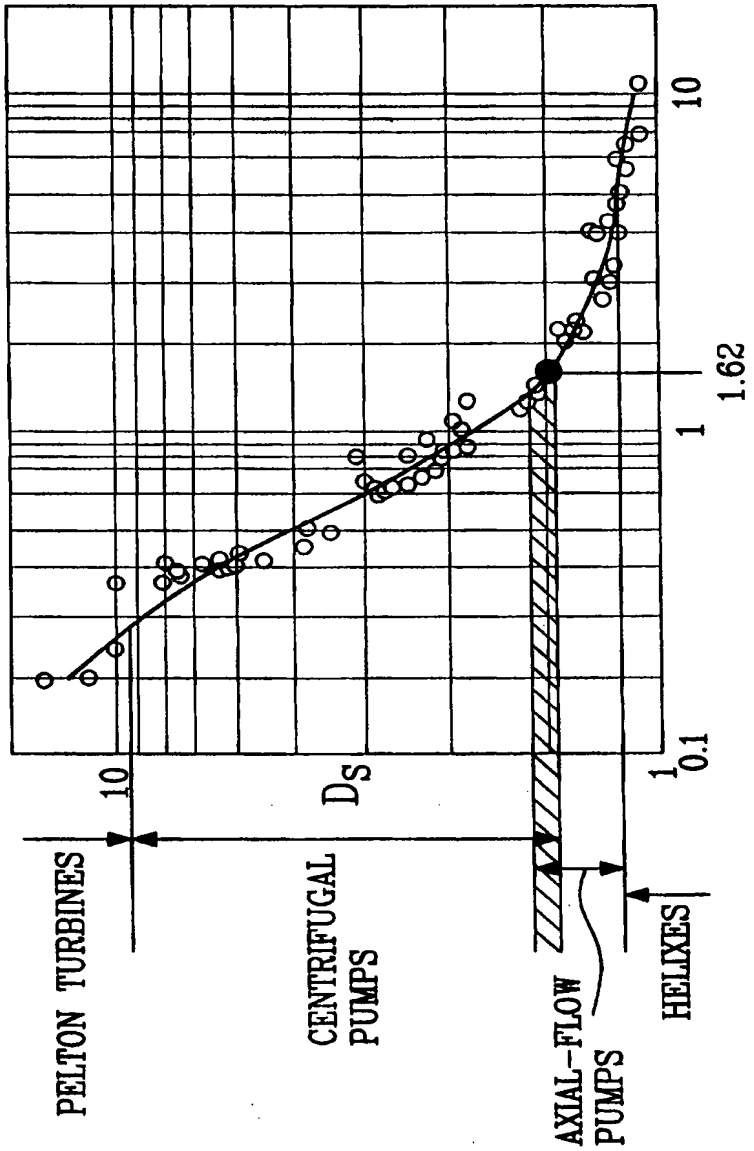

PELTON TURBINES
CENTRIFUGAL PUMPS
AXIAL-FLOW PUMPS
HELIXES
10
1
0.1
D_S
10
1
1.62
N_S

Fig-2

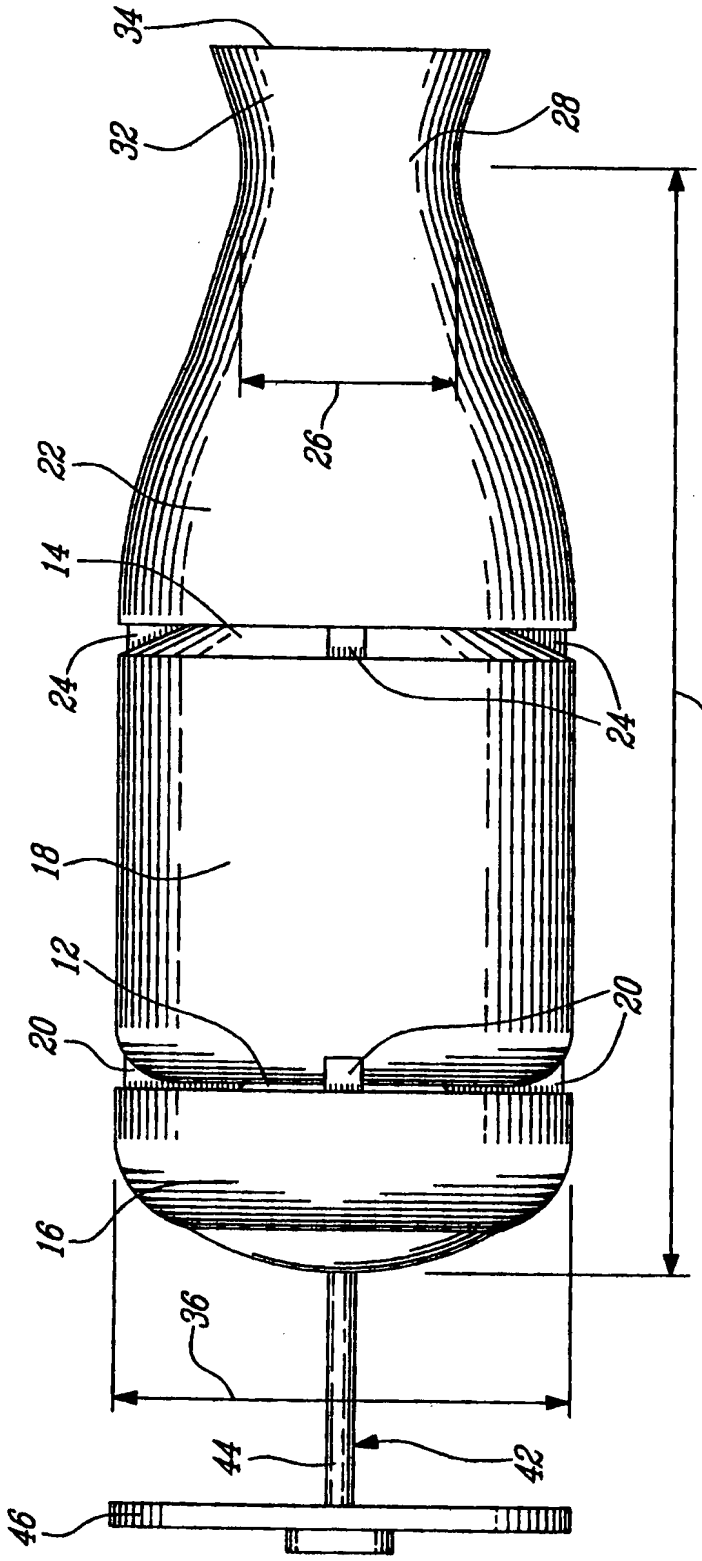
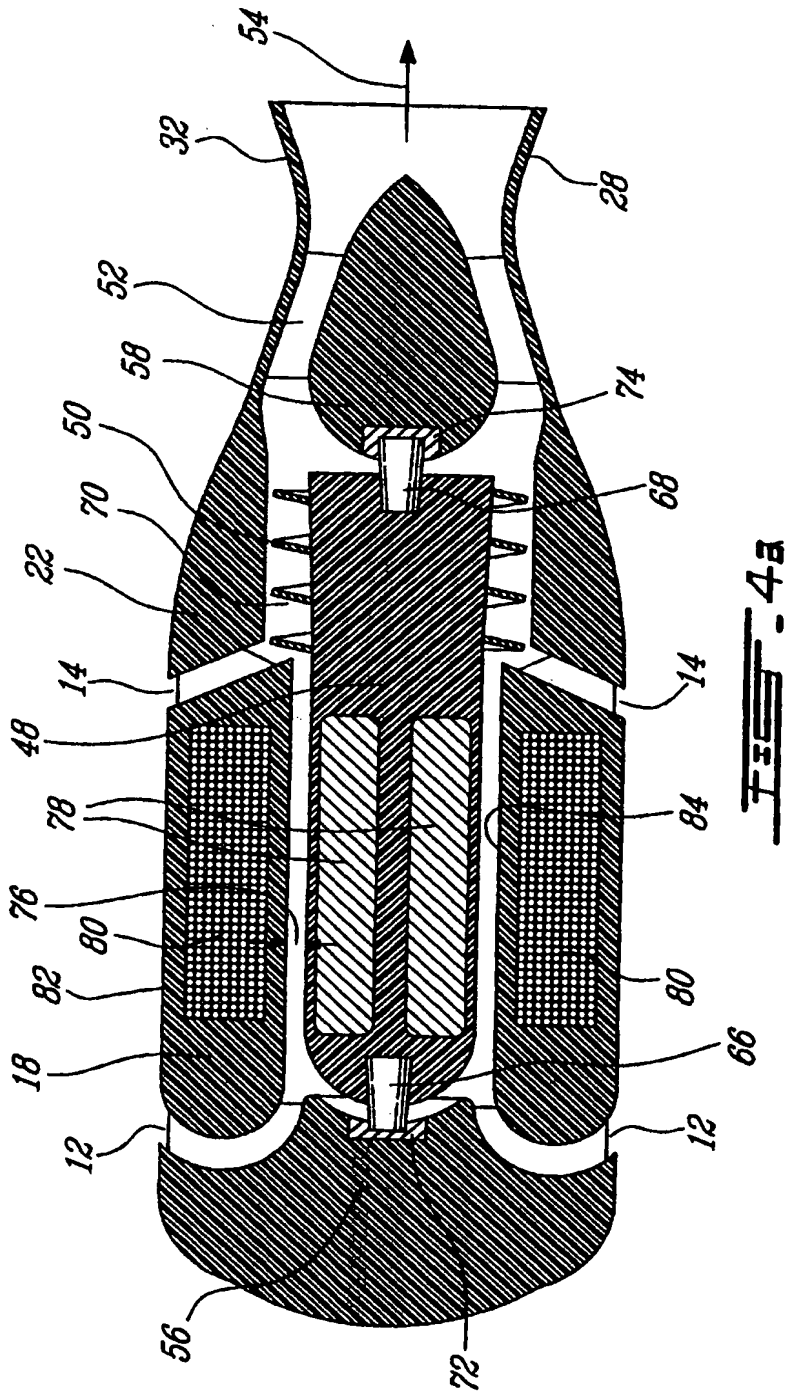


Fig. 3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32
28
52
58
74
50
70
68
22
14
14
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76
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80
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18
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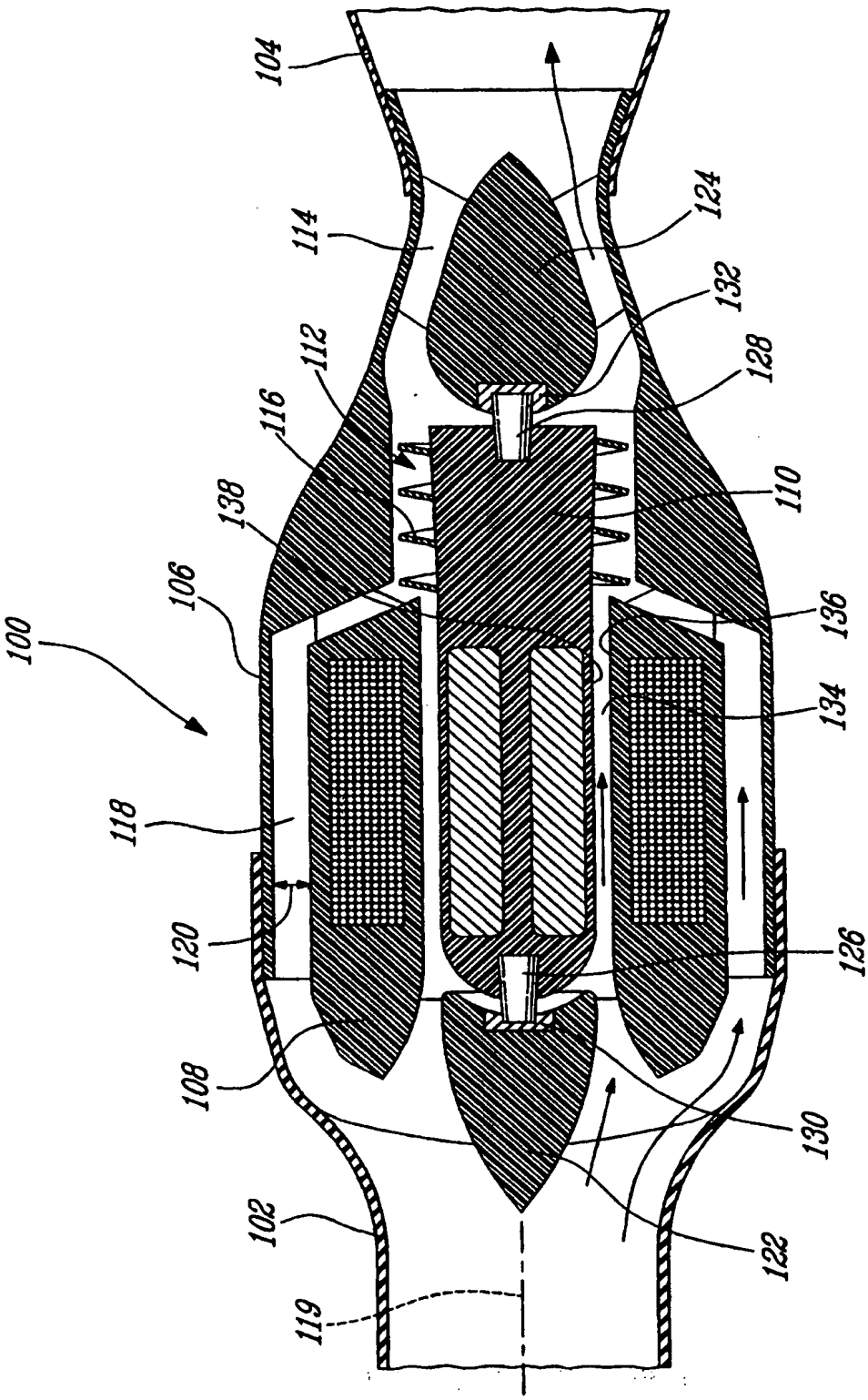
12
12
56
72

Fig. 4a


104
114
124
132
112
128
116
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136
100
134
118
120
126
108
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102
122
119

Fig. 4b

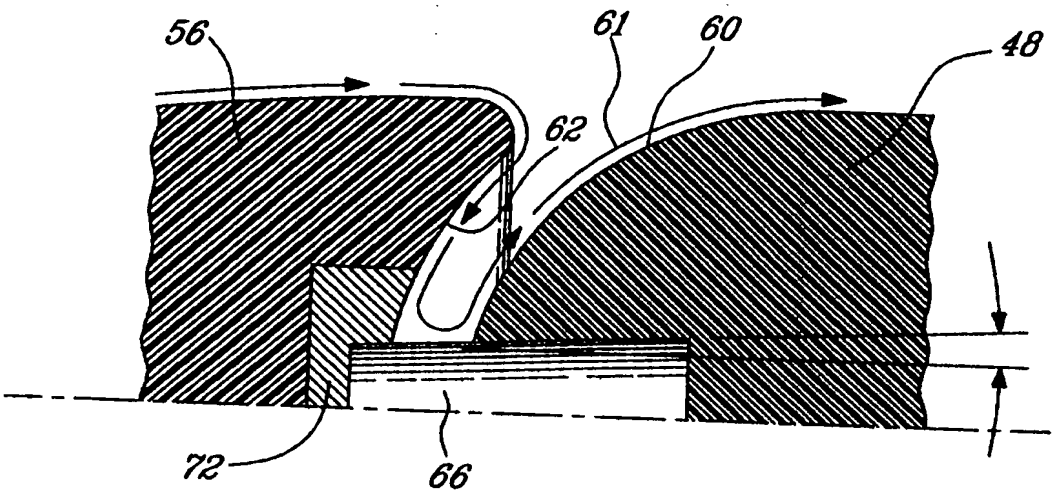

Fig. 5a

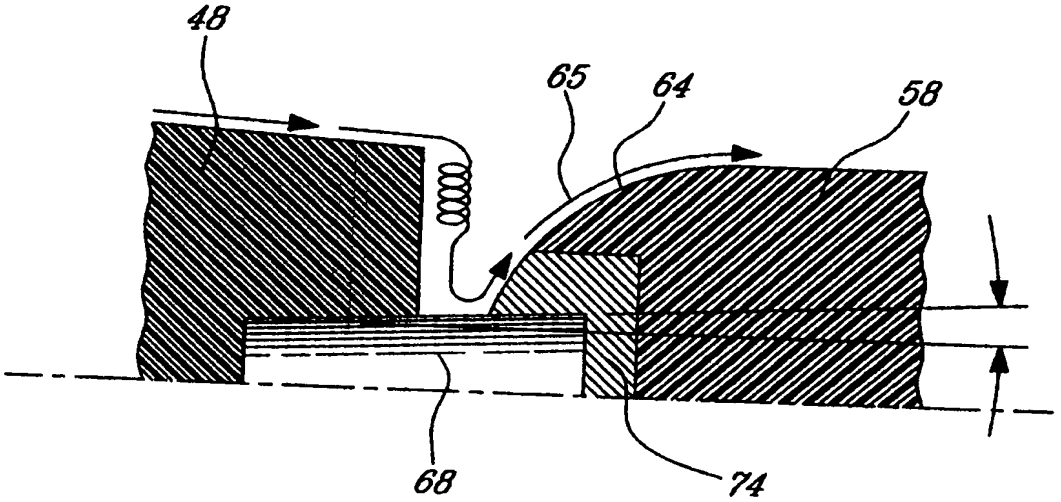

Fig. 5b

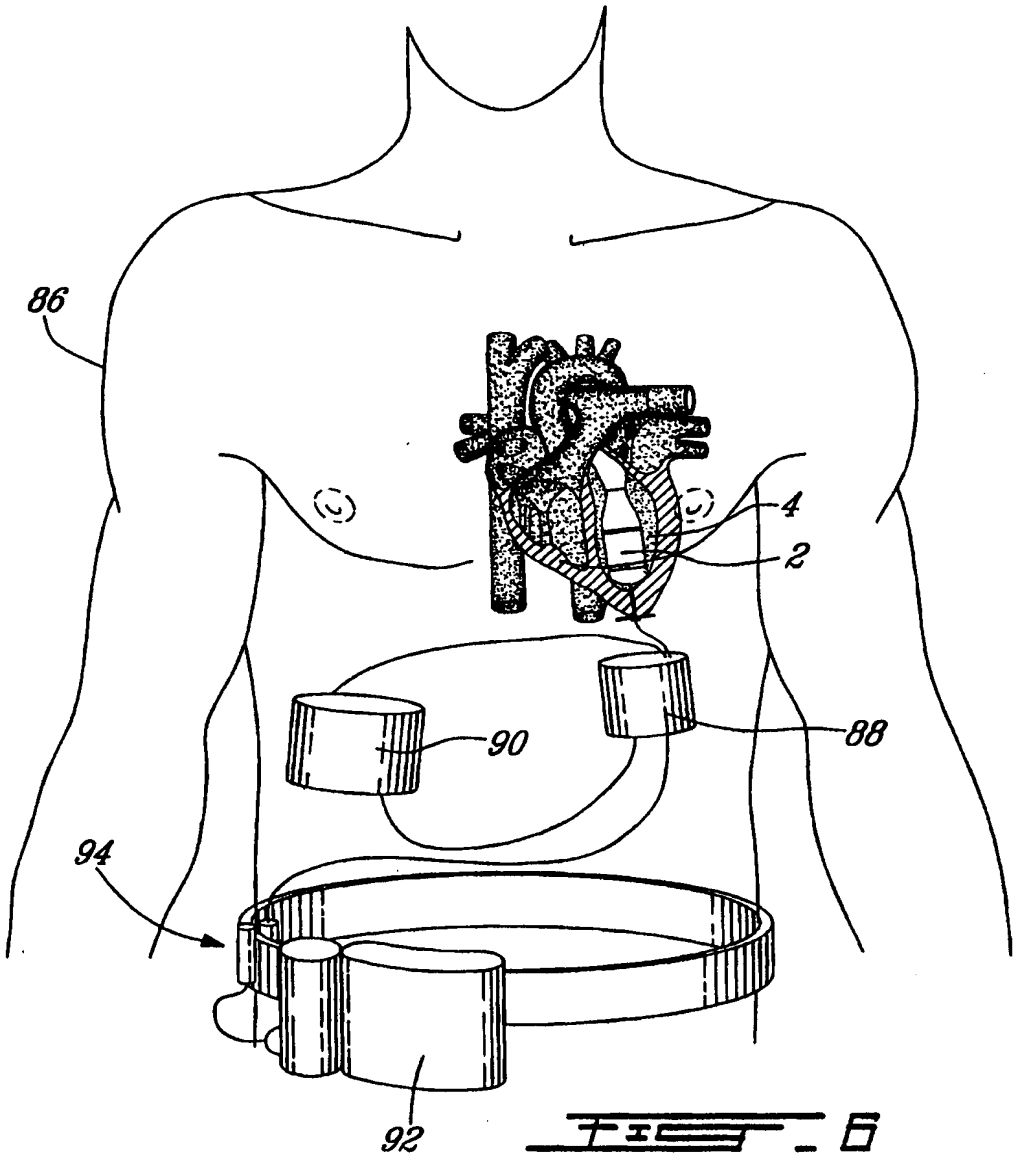

FIG. 6